201-14215

[illegible] 'OlsonAJ@[illegible].com>' on [illegible] 05/02/02 05:[illegible]22 PM

To: Rtk Chem/DC/USEPA/US@EPA, oppt.ncic@epamail.epa.gov
cc:

Subject: HPV Filing

Attached is the HPV filing for 2-Ethylhexyl Diphenyl Phosphate, CAS 1241-94-7.

Alan J. Olson
Director of Technology
Ferro Corp.


EDP HPV cl 123002.doc


EDPHVPtestplan 123002.doc

December 30, 2002
**Via email and FedEx**

Mr. Oscar Hernandez
Director, Risk Assessment Division (7403M)
U. S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460

Attn: Chemical Right-To-Known Program
Re: HPV Challange
2-Ethylhexyl Diphenyl Phosphate
CAS Registry Number 1241-94-7

Dear Mr. Hernandez:

As part of Ferro Corporation's commitment under EPA's High Production Volume (HPV) Challenge Program, Ferro is pleased to submit its proposed testing approach for 2-Ethylhexyl Diphenyl Phosphate. This submission consists of this cover letter, a Test Plan, and robust summaries for the existing studies available on 2-Ethylhexyl Diphenyl Phosphate.

Ferro understands that this Test Plan will be posted on the Internet and subject to a 120-day comment period. Ferro further understands that all comments by EPA or received by EPA will be forwarded to Ferro for consideration. In the event that additional information on existing studies of 2-Ethylhexyl Diphenyl Phosphate
becomes available to Ferro during the 120-day comment period, Ferro may wish to amend its submission.

This submission is also being sent electronically to the following e-mail addresses:

oppt.ncic@epa.gov
chem.rtk@epa.gov.

Thank you for your cooperation in this matter. If EPA requires any additional information about this submission, please contact me at 216-750-6696 or olsona@ferro.com.

Sincerely,

Alan J. Olson, P.E.
Director of Technology

201-14215A

# U.S. EPA HIGH PRODUCTION VOLUME CHEMICAL VOLUNTARY TESTING PROGRAM

## TEST PLAN

## 2-ETHYLHEXYL DIPHENYL PHOSPHATE

Submitted by:

FERRO CORPORATION
CLEVELAND, OHIO

December 2002

## INTRODUCTION

2-Ethylhexyl diphenyl phosphate, CAS Registry Number 1241-94-7, is a general purpose plasticizer for most commercial resins including polyvinyl chloride and its copolymers, cellulose nitrate, cellulose acetate-butyrate, ethyl cellulose, polymethyl methacrylate and polystyrene. 2-Ethylhexyl diphenyl phosphate (EDP) is approved for indirect food contact. EDP is a clear, odorless liquid with the following physical properties:

Boiling point 239 C ( 463°F)
Vapor pressure 0.195 kPa @ 150° C
Volatility 2.5% w/w ASTM D-2369
Viscosity 16.4 mPa @ 25°C
Solubility 0.31 mg/L @ 25°C.

## TEST PLAN RATIONALE

At this time, information available on the environmental effects, ecotoxicity and health effects of 2-ethylhexyl diphenyl phosphate cannot be documented or is judged to be not reliable according to the standards specified by Klimisch (Regulatory Toxicology and Pharmacology, 25, 1-5, 1997) or the EPA High Production Volume Challenge Program Guidelines for Determining the Adequacy of Existing Data (http://www.epa.gov/chemrtk/datadfin.htm). The exception to this is acute oral toxicity for which there is adequate data to satisfy this HPV Endpoint. A summary of those rodent oral data are included as Appendix 1 to this submission. Accordingly, Ferro Corporation commits to generating data, listed in Table 1, necessary to meet address HPV Endpoints.

Ferro Corporation is committed to providing EPA with reliable data necessary to complete the SIDS screening matrix for the HPV voluntary challenge; however, Ferro Corporation is also committed to judicious use of research animal resources. To this end Ferro Corporation will continue to attempt to obtain adequate documentation on existing studies of 2-ethylhexyl diphenyl phosphate. To the extent that this documentation becomes available to Ferro, the HPV Test Plan submitted herein may be altered to reflect reliance on existing studies.

## TEST PLAN: 2-ETHYLHEXYL DIPHENYL PHOSPHATE

Table 1 lists the HPV testing planned by Ferro Corporation for 2-ethylhexyl diphenyl phosphate.

Table 1: 2-ETHYLHEXYL DIPHENYL PHOSPHATE HPV TEST PLAN

| HPV DATA ENDPOINT | PROPOSED DATA DEVELOPMENT METHOD |
|---|---|
| 1. CHEMISTRY | |
| Melting Point | OECD Test Guideline 102 |
| Boiling Point | OECD Test Guideline 103 |
| Vapor Pressure | OECD Test Guideline 104 |
| Water Solubility | OECD Test Guideline 105 |
| Partition Co-Efficient | OECD Test Guideline 107 |
| 2. ENVIRON-MENTAL FATE | |
| Photodegradation | Estimate/model |
| Hydrolysis (Stability in Water) | OECD Test Guideline 111 |
| Biodegradation | OECD Test Guideline 301 |
| Fugacity | Fugacity Level III Modeling |
| 3. HEALTH EFFECTS | |
| Acute Toxicity | Information Available – No testing proposed |
| Repeat Dose Toxicity | Combined Repeat-Dose Toxicity Study with Reproductive/ Developmental Toxicity Screen: OECD Health Effects Test Guideline 422 |
| Repro-Develop. Toxicity | |
| Genetic Toxicity | Bacterial Mutation Test: OECD Health Effects Test Guideline 471<br>Mammalian Erythrocyte Micronucleus Test: OECD Health Effects<br>Test Guideline 474 |
| 4. ECOTOXICITY | |
| Fish | Acute Toxicity to Fish: OECD Test Guideline 203 |
| Daphnia | Acute Toxicity to Aquatic Invertebrates: OECD Test Guideline 202 |
| Algae | Acute Toxicity to Aquatic Plants (Algae): OECD Test Guideline 201 |

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APPENDIX 1

ROBUST SUMMARY OF ACUTE MAMMALIAN TESTING COMPLETED ON 2-ETHYLHEXYL DIPHENYL PHOSPHATE

Acute Oral Toxicity

| | |
|---|---|
| Test material: | 2-Ethylhexyl diphenyl phosphate (Lot K-2014) |
| Type: | LD50 |
| Species: | Rat |
| Strain: | Not Stated |
| Sex: | Male and female |
| Number of animals per dose level: | 4 of each sex, weight range 140-300g |
| Administration: | Single dose, oral gavage undiluted |
| Observations: | Body weight prior to dosing and at day 15 post-dose<br>Pharmacotoxic signs daily through day 15 post-dose<br>Survival |
| Results: | Acute oral LD50 > 24g/Kg |
| Reliability: | Reliable with restrictions |
| GLP: | Work conducted prior to inception of GLP regulations |
| Reference: | Kettering Laboratory of Applied Physiology Report, "A Comparison of the Toxic Effects of Lot K-2014 Santicizer #141 With That of a Previously Tested Lot", University of Cincinnati, March, 1949, Author, R. A. Kehoe. |

| | |
|---|---|
| Test material: | 2-Ethylhexyl diphenyl phosphate (Lot K-2014) |
| Type: | LD50 |
| Species: | Rat |
| Strain: | Not Stated |
| Sex: | Female and male |
| Number of animals per dose level: | 12, weight range 152-369g |
| Number of dose levels: | Two, 5 and 10g/Kg |
| Administration: | Twelve repeated doses - one dose daily for 12 consecutive days, oral gavage undiluted |
| Observations: | Body weight prior to dosing and at day 17<br>Pharmacotoxic signs daily through day 17<br>Survival |
| Results: | One animal in each dose group did not survive to the end of the dosing period. Pharmaocotoxic signs included soft stools, hair loss and skin irritation around anogenital area (reversible following cessation of dosing). Dose-related weight loss of up to 24%. Weight gain occurred in 21/22 animals following cessation of dosing. |
| Reliability: | Reliable with restrictions |
| GLP: | Work conducted prior to inception of GLP regulations |
| Reference: | Kettering Laboratory of Applied Physiology Report, "A Comparison of the Toxic Effects of Lot K-2014 Santicizer #141 With That of a Previously Tested Lot", University of Cincinnati, March, 1949, Author, R. A. Kehoe. |